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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/698,835

10/31/2003

Richard J. Arnott

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07/13/2006

MCKAY & ASSOCIATES, PC.

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PITTSBURG, PA 15226

EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/698,835

Applicant(s)

ARNOTT, RICHARD J.

Examiner

Jeffrey G. Hoekstra

Art Unit

3736

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Notice of Amendment***

1. In response to the amendment filed on 05/02/2006, amended claims 1, 7, and 9 and canceled claims 13-17 are acknowledged. The current rejections of the claims are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

### ***Claim Objections***

2. Claim 9 is objected to because of the following informalities:
3. The term "partially" is a relative term that appears to render the claim indefinite. The term "partially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The structural definition of the expanded portion defining the torque-assist area is unclear.
4. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The examiner notes a single claim that claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C.

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112, second paragraph. In *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990), a claim directed to an automatic transmission workstand and the method steps of using it was held to be ambiguous and properly rejected under 35 U.S.C. 112, second paragraph. In the instant case, claim 7 discloses both structural limitations directed towards a guidewire torquer apparatus and method of use limitations directed towards the interlocking of a guidewire in said torquer.

***Claim Rejections - 35 USC § 101***

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 7 embraces or overlaps two different statutory classes of invention. Such claims should be rejected under 35 U.S.C. 101 based on the theory that the claim is directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. *Id.* at 1551. See MPEP 2173.05(p).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshikawa (US D 333,182) in view of Christensen et al (US 2003/0229297 A1).

11. For claims 1-12, Yoshikawa shows a one-piece, disposable apparatus, as best seen in Figures 1-3 and 10, configured to aid in handling, steering, advancing, and positioning elongate structures through/into a vascular region, comprising: top and bottom arms, comprising: (a) a flexible connection between said top and bottom arms for releasably clamping via a flap hinge; (b) grips disposed on said top and bottom arms on the outer facing surfaces comprising expanded portions disposed as torque assisting areas; (c) proximal and distal holes comprising a wire channel for threading/positioning an intra-vasculature device when said top and bottom arms are clamped wherein said proximal slit is horizontally disposed within said flap hinge and said distal slit is disposed within said clamping tongue; (d) a bottom lip disposed on said bottom arm's outer face;

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(e) a clamping tongue disposed downwardly from said top arm wherein said clamping tongue further comprises an integrally formed tongue clip projecting upwardly and inwardly and configured to snap onto said bottom lip for releasably clamping said flap hinge; and (f) said wire channel means further comprising multiple and alternating projections integrally formed and in a spaced relation along said top and bottom arms.

12. Yoshikawa discloses the claimed invention except for the guidewire torquer apparatus comprising (a) a horizontally defined proximal slit disposed within half the width of the flap hinge, (b) a vertically defined distal slit disposed within half the length of the clamping tongue, and (c) the wire channel projections having longitudinal grooves disposed thereon. Christensen et al teaches a guidewire torquer apparatus 10, comprising: (a) a horizontally defined proximal slit 20 disposed within half the width of a flap hinge (paragraph 21, page 2 right column), (b) a vertically defined distal slit 19 disposed within half the length of a clamping tongue (paragraph 21), and (c) wire channel projections 23 having longitudinal grooves disposed thereon (paragraph 24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire torquer apparatus as taught by Yoshikawa, with the slits and projections as taught by Christensen et al for the purpose of configuring a guidewire torquer for increased mechanical control during advanced surgical procedures requiring the navigation of tortuous vasculature.

***Response to Arguments***

13. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

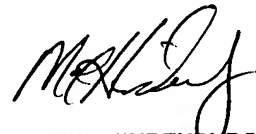
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JGH

JH



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